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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,488	07/05/2001	Barry John Langham	CELL-0113	2595

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EXAMINER

MCKENZIE, THOMAS C

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 08/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/899,488

Applicant(s)

LANGHAM ET AL.

Examiner

Thomas McKenzie, Ph.D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21,23,24 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19 and 27 is/are allowed.
- 6) ☒ Claim(s) 1-12,14-18,20,21,23 and 24 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview-Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to amendments filed on 6/4/03. Applicant has amended claims 1, 15, 16, 19, and 21. Applicants have canceled claims 25 and 26. There are twenty-four claims pending and twenty-four under consideration. Claims 1-19 and 27 are compound claims. Claim 20 is a composition claim. Claims 21, 23, and 24 are use claims. All pending claims were previously rejected. This is the second action on the merits. The application concerns some cyclobut-3-en-1,2-dione compounds, compositions, and uses thereof.

Response to Amendment

2. Applicants' deletion of claims 25 and 26 overcomes the indefiniteness rejection made in point #6 of the previous office action. Applicants' deletion of solvates from the claims overcomes the enablement rejection made in point #7. Applicants' deletion of MS treatment overcomes the enablement rejection made in point #8. The two terminal disclaimers overcome the double patenting rejections made in points #9 and #10.

Information Disclosure Statement

3. The information disclosure statement filed 1/6/03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Applicants' comments concerning these references and the copy of the receipt are noted. A second search has been ordered but the references have not been found.

Claim Rejections - 35 USC § 112

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 1-12, 14-18, 20, 21, 23, and 24 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The words, in the definition of R² spanning pages 3-4 of the recent amendment "heterocycloalkyl", "heterocycloalkenyl", "bicycloheteroalkyl", "bicycloheteroalkenyl", "tricycloheteroalkyl", and "tricycloheteroalkenyl", are indefinite. Applicants do not define any of these terms in the specification. Firstly, while applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947), *Ex Parte Clifford*, 63 USPQ 19, and MPEP 2173.01. Secondly, there is no such thing as a heterocycloalkyl radical. The art recognized meaning of cycloalkyl is a monocyclic hydrocarbon that contains only single bonds. It may not contain heteroatoms. Is "heterocycloalkyl" an alkyl substituted by a heterocycle, e.g. pyridyl-methyl? A cycloalkyl interrupted by a heteroatom, such as piperidinyl? A

cycloalkyl substituted by a heteroatom, e.g. methoxycyclopropyl? Whatever choice is selected must be supported by the specification. The definition of cycloalkyl, which Applicants provide in lines 1-7, page 9 does not include the possibility of hetero atoms inserted into the carbon ring and does not distinguish between the other two possibilities. Lines 23-28, page 15 Applicants discuss "heterocycloaliphatic" and heterocycloalkyl". The definition is circular, uses open terms, and fails to address where the heteroatom is attached. Furthermore, in lines 9-15, page 9 Applicants offer piperidinyl as an example of a "heterocyclic ring", implying that a "heterocycloalkyl" must be something different.

Applicants argue that the skilled organic chemist would understand the meaning of the term. In support of the argument, they supply dictionary definitions of the terms "cycloalkyl" and "heterocyclic". This is not persuasive. Firstly, there is no dispute about the meaning of "cycloalkyl" and "heterocyclic". What does "heterocycloalkyl" mean? Neither dictionary used by Applicants contains the term "heterocycloalkyl" which is at issue. Neither definition used above clarifies what is intended. Secondly, in the previous action, the Examiner asked about some possible but contradictory meanings of the term as understood by the average skilled organic chemist. If Applicants cannot answer the questions, then how is that chemist to understand their meaning?

Thirdly, when an Applicant chooses to be their own lexicographer and uses and defines terms with special meanings, then Applicant must set out the definition explicitly. If he defines the specific terms used to describe the invention, this must be done "with reasonable clarity, deliberateness, and precision". "The patentee may demonstrate an intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope", *Teleflex Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374. "[P]atentee is free to be his own lexicographer, so long as the special definition of a term is made explicit in the patent specification or file history." *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1851. See *SciMed*, 58 USPQ2d at 1065 and MPEP 2111.01. Pursuant to 35 USC 112, paragraph two, "[i]t is the applicants' burden to precisely define the invention, not the PTO's", *In re Morris* 44 USPQ2d 1023. Applicants' specification lacks the clear and precise definitions required of the disputed terms.

Allowable Subject Matter

5. Claims 19 and 27 are allowed. Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 1-12, 14-18, 20, 21, 23, and 24 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

7. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (703) 308-9806. The FAX number for after final amendments is (703) 872-9307. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mukund Shah can be reached on (703) 308-4716. Please direct general inquiries or any inquiry relating to the status of this application to the receptionist whose telephone number is (703) 308-1235.

Mukund Shah

Mukund Shah
Supervisory Patent Examiner
Art Unit 1624

TCMcK
August 1, 2003

